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Department of Health Services
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California Morbidity

State of California
Pete Wilson, Governor

Adverse Reactions Cause the Department of Health Services to Require a Label Notice on Foods and Dietary Supplements Containing Ingredients with Stimulant Laxative Effects

In 1987, the California Department of Health Services' Food and Drug Branch (FDB) began receiving sporadic complaints of gastrointestinal disturbances from consumers of "dieter's" teas containing senna. Communication with the U. S. Food and Drug Administration revealed 67 consumer complaints between 1982 to 1992 from individuals who had drunk "dieter's" teas. First-time consumers generally complained of unexpected abdominal cramps and diarrhea, at times severe and lasting several days. Repeat consumers complained of persistent abdominal pains, muscle weakness, electrolyte disturbances, and impaired bowel function.

Between 1992 and 1994, FDB learned of four deaths (one in California) in otherwise healthy young women who reportedly drank senna-containing teas for months to years before they died. FDB asked the Department's Environmental Health Investigations Branch (EHIB) for assistance in evaluating these deaths. EHIB's evaluation concluded that it would be difficult to determine that the teas caused these deaths, but the teas could exacerbate low blood potassium (hypokalemia). Potential consequences of hypokalemia include muscle weakness, permanent kidney damage, and life-threatening cardiac arrhythmias.[1] Two of these four deaths resulted from cardiac arrhythmias during episodes of hypokalemia.

To investigate the relationship between senna-containing teas and the adverse reaction reports, the Department measured quantities of stimulant laxative chemicals (sennosides A and B) in nine brands of senna-containing teas. Seven brands are sold as foods (including several flavors of some brands) and two brands are sold as over-the-counter (OTC) stimulant laxative drugs. The Department tested for sennosides A and B in teas containing senna because these teas were the types of products most complained about and results could be compared with the amounts of sennosides A and B found in OTC stimulant laxative drugs. OTC stimulant laxative drugs containing senna are considered safe and effective for the treatment of occasional constipation provided that they contain between 12 to 50 milligrams (mg) sennosides A and B to be taken once or twice a day.[2] The two brands of tea sold as OTC stimulant laxative drugs, when prepared according to label directions, contained 7 and 10 mg sennosides A and B per cup, below the quantities specified for OTC drugs. All seven brands of tea sold as foods, when prepared according to label directions (or sometimes for shorter times than directed on the label), contained quantities of sennosides A and B in the range specified for OTC stimulant laxative drugs. One brand of "dieter's" tea steeped for 5 minutes as directed on the label contained 19 mg sennosides A and B per cup.

Even though teas and dietary supplements may contain levels of sennosides A and B in the range of OTC stimulant laxative drugs, they can be sold as foods if their intended use is for flavor, nutrition, or aroma (food uses) and not to diagnose, cure, mitigate, treat, or prevent diseases (drug uses). The use of senna as flavorings in food is limited to the minimum quantity required to produce the intended physical or technical effect.[3] Federal law limits the use of senna in dietary supplements to levels that do not present a significant or unreasonable risk of illness or injury.[4] But there are no specific upper limits for either use.

Although most people reporting adverse reactions consumed teas containing senna, there are at least six herbs (aloe, buckthorn, cascara, frangula, rhubarb root, and senna) used in foods or dietary supplements that contain chemicals known as anthraquinones, like sennosides A and B, that can have stimulant laxative effects.[5] Ingestion of any of these herbs poses the same potential health risks. A market survey conducted by FDB found teas and dietary supplements that contained each of these herbs.

On January 1, 1997, the Department adopted emergency regulations requiring a label statement on foods and dietary supplements containing any amount of aloe, buckthorn, cascara, frangula, rhubarb root, or senna.

These regulations were finalized on March 1, 1998, and require the label statement shown below on the package of any food or dietary supplement sold in California containing aloe, buckthorn, cascara, frangula, rhubarb root, or senna.

> NOTICE: This product contains (name of substance(s) and common name(s) if different). Read and follow directions carefully. **Do not use if you have or develop diarrhea, loose stools, or abdominal pain because (insert common name) may worsen these conditions and be harmful to your health.** Consult your physician if you have frequent diarrhea or if you are pregnant, nursing, taking medication, or have a medical condition.

Please direct any questions or comments regarding this regulation to Susan Loscutoff, Ph.D., D.A.B.T., FDB Staff Toxicologist, at (916) 327-8039, or e-mail to sloscuto@fdb.dhs.cahwnet.gov.

References

[1] *Scientific American Medicine*, 10, II, 19, January 1993.

[2] 51 *Federal Register* 35316-7, October 1, 1986, Food and Drug Administration, Laxative Drug Products for Over-the-Counter Human Use - Tentative Final Monograph.

[3] Title 21, *Code of Federal Regulations*, Section 172.510(a).

[4] *Federal Food, Drug, and Cosmetic Act*, 21 U.S.C., Section 342(f)(1)(A)

[5] *Adverse Effects of Herbal Drugs*, P.A.G.M. DeSmet (editor), Anthranoid Derivatives - General Discussion, Wes 105-118, Springer-Verlag, 1993.

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